

July 08, 2020

Title: Closed Government-to-Government Meeting with Agreement States to Discuss Radiopharmaceutical Extravasation and Medical Event Reporting

Date(s) and Time(s): July 23, 2020, 02:00 PM to 03:30 PM

Location: Webinar

Category: This is a Closed meeting. Is a general information exchange having no direct, substantive connection to a specific NRC regulatory decision or action.

Purpose: To discuss with Agreement State officials in a closed, government-to-government forum, the U.S. Nuclear Regulatory Commission (NRC) staff's planned evaluation of whether and how radiopharmaceutical extravasations should be reported as medical events.

Contact: Sarah Lopas
301-415-6360
Sarah.Lopas@nrc.gov

Participants:	<u>NRC</u>	<u>External</u>
	Office of Nuclear Material Safety and Safeguards Office of General Counsel	Agreement State Officials, Organization of Agreement States

Comments: Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Currently, the NRC does not classify radiopharmaceutical extravasations as medical events and thus does not require them to be reported to the agency. However, considering recent and anticipated advancements in nuclear medicine, the NRC staff is reevaluating this position. Please see the attached report to Congress, "Updates to Injection Quality Monitoring, Classification, and Reporting Requirements for Extravasations" (ML20050W303) for more information.

PUBLIC MEETING AGENDA

Closed Government-to-Government Meeting with Agreement States to Discuss Radiopharmaceutical Extravasation and Medical Event Reporting

July 23, 2020, 02:00 PM to 03:30 PM

Webinar

<i>Time</i>	<i>Topic</i>	<i>Speaker</i>
2:00 p.m.	Welcome and Introduction	Chris Einberg, NRC
2:05 p.m.	Meeting Logistics	Sarah Lopas, NRC
2:10 p.m.	Background Information on Extravasations	Lisa Dimmick, NRC
		Said Diabes, NRC
2:20 p.m.	Staff's Planned Evaluation and Review of Petition for Rulemaking on Extravasations	Lisa Dimmick, NRC
		Daniel Dimarco, NRC
2:30 p.m.	Questions and Comments from Agreement States	All Attendees

The time of the meeting is local to the jurisdiction where the meeting is being held.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If reasonable accommodation is needed to participate in this meeting, or if a meeting notice, transcript, or other information from this meeting is needed in another format (e.g., Braille, large print), please notify the NRC meeting contact. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

ADAMS Accession Number: ML20190A200

Distribution:

R. Lewis, NMSS

M. Layton, NMSS

NMSS/MSST/SALPB

NMSS/MSST/MSEB

J. Weil, OCA

J. McIntyre, OPA

Name	Sarah Lopas	Duane E. White
Office	NMSS/MSST/MSEB/P M	NMSS/MSST/MSEB/B C
Date	07/07/2020	07/08/2020

OFFICIAL RECORD COPY